

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION**

<b>RENE LEACH, et al.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>vs.</b>	)	<b>Cause No. 1:18-cv-1185-WTL-MJD</b>
	)	
<b>BAYER CORPORATION, et al.,</b>	)	
	)	
<b>Defendants.</b>	)	

**ENTRY ON MOTION TO REMAND**

This cause is before the Court on the Plaintiffs’ motion to remand. Dkt. No. 7. The motion is fully briefed and the Court, being duly advised, **GRANTS** the motion for the reasons set forth below.

The Plaintiffs filed this case in state court in Marion County, Indiana. In their Complaint, the Plaintiffs brought nine causes of action related to alleged injuries suffered by the Plaintiffs as a result of the implantation of a medical device, Essure. Essure is a permanent contraceptive device designed by the Defendants, subject to federal laws such as the Medical Device Amendments and the Federal Food Drug and Cosmetics Act of 1938. Of the claims raised by the Plaintiffs, seven assert violations of the Indiana Products Liability Act, one a violation of the Uniform Commercial Code, and one a violation of Indiana’s Consumer Sales Act. The Defendants removed the case to this Court, asserting that “because Plaintiffs’ claims relate to a medical device with premarket approval that is heavily regulated by FDA and Plaintiffs’ claims turn on the interpretation of federal law, . . . this case arises from and turns on a question of federal law.” Dkt. No. 1 at 4. The Plaintiffs now move to remand. The Defendants do not assert

a right to remove based on diversity jurisdiction, making the sole question whether removal was proper with regard to federal question jurisdiction, *see* 28 U.S.C. §§ 1331 and 1441.

As the Supreme Court has noted, “a case can arise under federal law in two ways.” *Gunn v. Minton*, 568 U.S. 251, 257 (2013) (internal quotation marks and alteration omitted). First, “a case arises under federal law when federal law creates the cause of action asserted.” *Id.* at 257. That is not the case here because the Plaintiffs have pled nine state-law causes of action. Second, a case may arise under federal law “if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Id.* at 258. This is a “‘special and small category’ of cases.” *Id.* (quoting *Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006)). The question here is whether this is such a case.

The first factor to consider is whether the Plaintiffs’ claims necessarily raise a federal issue. Unfortunately for the Defendants, this is not the case. While federal law may be applied, it is not necessarily presented. This is because “the complaint itself will not avail as a basis of jurisdiction in so far as it goes beyond a statement of the [Plaintiffs’] cause[s] of action and anticipates or replies to a probable defense.” *Gully v. First Nat’l Bank*, 299 U.S. 109, 112 (1936). The Plaintiffs explicitly state that they have “plead[ed] *to avoid* [the Defendants’] *affirmative defense* of ‘express’ preemption under the Medical Device Amendments to the Federal Food Drug and Cosmetics Act of 1938.” Dkt No. 8 at 9 (emphasis in original). In response, providing several examples of the Plaintiffs’ statements of federal law, the Defendants argue that “the federal issues are not merely anticipating a preemption defense; they are an essential part of Plaintiffs’ causes of action as pleaded.” Dkt. No. 16 at 6-8. Despite these examples, however, the Defendants fail to articulate how these allegations are required under

Indiana state law, as opposed to being a necessary response to a likely preemption defense. “Preemption is an affirmative defense,” *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010), and, following *Gully*, the Plaintiffs are allowed to plead in anticipation of the defense being raised. Thus, remand is appropriate.

The Defendants cite *Merrill Lynch, Pierce, Fenner & Smith Inc. v. Manning*, 136 S. Ct. 1562 (2016), *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308 (2005), *Franchise Tax Bd. of State of Cal. v. Constr. Vacation Tr. for S. Cal.*, 463 U.S. 1 (1983), and *Smith v. Kansas City Title & Tr. Co.*, 255 U.S. 180 (1921), to support the proposition that the Plaintiffs’ claims necessarily present federal issues because the success of the Plaintiffs’ claims depends on their ability to show violations of federal law. Dkt. No. 16 at 5. However, as discussed above, it is not the Plaintiffs’ claims which depend on federal law, but rather the Defendants’ affirmative defense of preemption. *See Bausch*, 630 F.3d at 552 (recognizing that preemption “protects a medical device manufacturer from liability to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law”). In *Franchise Tax Bd.*, cited by the Defendants, the Supreme Court recognized that allegations relating to an affirmative defense may make it “‘very likely, in the course of the litigation, a question under the Constitution would arise, [but] do not show that the suit, that is, the [Plaintiffs’] original cause[s] of action, arise[] under the Constitution.’” *Franchise Tax Bd. of State of Cal.*, 463 U.S. at 10 (quoting *Louisville & Nashville R. Co. v. Mottley*, 211 U.S. 149, 152 (1908)).

In contrast, the cases cited by the Defendants necessarily turn on federal law. *Merrill Lynch*, for example, involved the interpretation of Section 27 of the Securities Exchange Act of 1934, which grants federal district courts exclusive jurisdiction “‘of all suits in equity and actions


at law brought to enforce any liability or duty created by [the Exchange Act] or the rules or regulations thereunder.” 136 S. Ct. at 1566 (alteration in original) (quoting 15 U.S.C. § 78aa(a)). Recognizing this broad jurisdictional grant, the Supreme Court found federal jurisdiction over “a state-law cause of action [] ‘brought to enforce’ a duty created by the Exchange Act,” *id.* at 1570, but even still acknowledged that their holding did “nothing to prevent state courts from resolving Exchange Act questions that result from defenses or counterclaims,” *id.* at 1574. Here there is no such broad jurisdictional hook, and, following *Merrill Lynch*, remand is appropriate because an affirmative defense may not establish federal jurisdiction.

*Grable* and *Smith*, meanwhile, were challenges to federal actions or laws, as opposed to state-law tort claims subject to federal law limitations. In the Supreme Court’s own words, the “principal issue in [*Smith*] was the federal constitutionality of [a] bond issue.” *Grable & Sons Metal Prods., Inc.*, 545 U.S. at 312. Meanwhile, the Seventh Circuit has noted that the state proceeding in *Grable* “amounted to a collateral attack on a federal agency’s action.” *Bennett v. Southwest Airlines Co.*, 484 F. 3d 907, 909 (7th Cir. 2007). *Bennett* is particularly apt in that it involved a state-law tort claim in a field, aviation, highly regulated by federal law. In that case, the Seventh Circuit was faced with “a fact-specific application of rules that come from both federal and state law rather than a context-free inquiry into the meaning of a federal law,” *id.* at 910, and remanded because “the national regulation of many aspects of air travel [does not mean] that a tort claim in the wake of a crash ‘arises under’ federal law,” *id.* at 912. Faced with a similar inquiry into the field of medical devices, the Court must remand this case as well.

Because the Plaintiffs’ claims do not arise under federal law, this case was improperly removed. Accordingly, the Plaintiffs’ motion to remand is **GRANTED** and this case is **REMANDED** to the Marion County Superior Court. **As required by 27 U.S.C. § 1447(c), the**

**Clerk shall mail a certified copy of this remand order to the Clerk of the Marion County  
Superior Court.**

SO ORDERED: 7/18/18

A handwritten signature in black ink, reading "William T. Lawrence", is written over a horizontal line.

Hon. William T. Lawrence, Judge  
United States District Court  
Southern District of Indiana

Copies to all counsel of record via electronic notification